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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/089,583	06/03/98	WEISMAN K	[redacted]

HM32/0810

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EXAMINER	
OWENS T	

ART UNIT	PAPER NUMBER

DATE MAILED: 08/10/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/089,583	Weisman et al.
Examiner	**Group Art Unit**
Howard Owens	1623

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-14 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-14 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim Objections

The terms Bicalutamide, Flutamide and Nilutamide in claims 5, 7, 8, 10, 11 and 13 are not species of microorganisms, as such they do not require underlining.

For clarity, use of the abbreviations LHRH or GnRH in claim 2 while accepted art abbreviations should be set forth initially as the full written terms (said abbreviations are intended to represent).

Specification

The specification does not conform to the preferred arrangement of a patent application for prosecution in front of the United States Patent and Trademark Office. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the title of the invention,

each of the lettered items should be preceded by the headings indicated below.

(a) Title of the Invention(See 37 C.F.R. § 1.72(a). The title of the invention should be placed at the top of the first page of the specification. It should be brief but technically accurate and descriptive, preferably from two to seven words.
(b) Cross-References to Related Applications (if any).
© Statement as to rights to inventions made under Federally-sponsored research and development (if any).
(d) Background of the invention.
1. Field of the Invention.
2. Description of the Related Art including information disclosed under 37 C.F.R. §§ 1.97-1.99.
(e) Summary of the Invention.
(f) Brief Description of the Drawing.
(g) Description of the Preferred Embodiment(s).
(h) Claim(s).
(I) Abstract of the Disclosure.

Abstract Objected to: Minor Informalities

The Abstract of the Disclosure is objected to because applicant's use of the term "substance" in the abstract is too nonspecific and does not provide the general nature of the compound or class of compounds.

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts, compounds or compositions, the general nature of the compound or composition should be given as well as its use, *e.g.*, "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary. Complete

revision of the content of the abstract is required on a separate sheet.

Trademarks and Their Use

The use of the trademarks ZOLADEX and CASODEX have been noted in this application. These and other trademarks not noted should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Reference in 1.60 Continuing Applications

This application filed under 37 C.F.R. § 1.60 lacks the necessary reference to the prior application. A statement reading "This is a continuation of provisional application Serial No. 60/041,070, filed 3/18/97" should be entered following the title of the invention or as the first sentence of the specification.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982);

In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CAR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CAR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CAR 3.73(b).

Claim 3 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 09042273. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are methods of decreasing atherosclerosis and its complications through the administration of Finasteride. Applicant seeks to broaden the scope of the of the claim set forth in copending Application No. 09042273 by further applying a class of compounds in addition to the member Finasteride as an agent of decreasing atherosclerosis. One of skill would be provided with a motivation or suggestion to use other members of that class of compounds for treatment of a condition.

The test of the patentability of a method directed to a new use of an old compound is the unobviousness of that new use. If the result of the process is unobvious and the particular use of the material is not suggested by the prior art, the process is patentable. In the case of the instant application, given that

Finasteride and associated 5-alpha reductase inhibitors are known to inhibit the conversion of testosterone to dihydrotestosterone and applicant seeks patentability of the instant method claims based on this, or lowered testosterone levels, even though the administration of 5-alpha reductase inhibitors has not been shown to reduce testosterone levels, only the conversion of testosterone to dihydrotestosterone (Goodman and Gilman's The Pharmacological Basis of Therapeutics, p. 1428).

Thus it would be obvious that one of skill in the art would be motivated or at least be provided with an adequate suggestion to use associated 5-alpha reductase inhibitors to treat atherosclerosis or its complications if claim 1 of the 09/042,273 application were found to be allowable.

102(e)/103(a)

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. Applicant has provided evidence in this file showing that the invention was owned by, or subject to an obligation of assignment to, the same entity as 09042273 at the time this invention was made. Accordingly, 09042273 is disqualified as prior art through 35 U.S.C. 102(f) or (g) in any rejection under 35 U.S.C. 103(a) in this application. However, this applied art additionally qualifies as prior art under subsection (e) of 35

U.S.C. 102 and accordingly is not disqualified as prior art under 35 U.S.C. 103(a).

Applicant may overcome the applied art either by a showing under 37 CAR 1.132 that the invention disclosed therein was derived from the invention of this application, and is therefore, not the invention "by another," or by antedating the applied art under 37 CAR 1.131.

Claim 3 is provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 09042273 which has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future patenting of the conflicting application. The test of the patentability of a method directed to a new use of an old compound is the unobviousness of that new use. If th result of the process is unobvious and the particular use of the material is not suggested by the prior art, the process is patentable. In the case of the instant application, given that Finasteride and associated 5-alpha reductase inhibitors are known to inhibit the conversion of testosterone to dihydrotestosterone and applicant seeks patentability of the instant method claims based on this, or lowered testosterone levels, even though the

administration of 5-alpha reductase inhibitors has not been shown to reduce testosterone levels, only the conversion of testosterone to dihydrotestosterone (Goodman and Gilman's The Pharmacological Basis of Therapeutics, p. 1428).

Thus it would be obvious that one of skill in the art would be motivated or at least be provided with an adequate suggestion to use associated 5-alpha reductase inhibitors to treat atherosclerosis or its complications if claim 1 of the 09/042,273 application were found to be allowable. Applicant seeks to broaden the scope of the of the claim set forth in copending Application No. 09042273 by further applying a class of compounds in addition to the member Finasteride as an agent of decreasing atherosclerosis. One of skill would be provided with a motivation or suggestion to use other members of a class of compounds for treatment of a condition.

This provisional rejection might be overcome either by a showing under 37 CAR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CAR 1.131.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant specification invites the skilled artisan to experiment. The factors which must be considered in determining undue experimentation are set forth in In re Wands 8USPQ 2d 1400. The factors include:

1) quantity of experimentation necessary,
2) the amount of guidance presented,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the predictability of the art,

7) breath of the claims and the

8) level of skill in the art.

Quantity of experimentation necessary, Amount of guidance presented, Presence or absence of working examples

Claims 1-14 are drawn to a method of decreasing atherosclerosis and its complications via administration of finasteride, inhibitors of LHRH or GnRH, bicalutamide, flutamide and nilutamide.

Applicant has not provided significant data which clearly shows humans or animals where there is a clear correlation between clearly documented atherosclerotic conditions wherein administration of said agents solely reduced or decreased these conditions. Applicant has not supplied adequate comparative data showing isolation of factors such as age, weight and dietary intake, presence or absence of other drugs and genetic factors. As all of these factors may contribute significantly to atherosclerosis and associated conditions, one of skill in the art would be left to undue experimentation in determining the efficacy of these agents in reducing atherosclerosis and associated conditions. Applicant's working examples are based on a retrospective study and not a closely monitored and controlled clinical trial.

Predictability of the art/State of the art

According to Goodman and Gilman's The Pharmaceutical Basis of Therapeutics, interpatient and intrapatient variation in disposition of a drug must be taken into account in choosing a drug regimen. Different individuals vary in the magnitude of their response to the same concentration of a single drug or to similar drugs when the appropriate correction has been made for differences in potency, maximal efficacy and slope (pp 65-68). The prior art indicates that climacteric disorders during aging in males such as increased incidence of cardiovascular diseases may be associated with the reduction in testosterone or steroid precursor levels (U.S. Patent No. 5872114, col.3-col.4; U.S. Patent no. 5,906,987, col. 1-col.2). Thus the state of the art requires a well designed and well executed clinical trial wherein homogenous populations of patients must be selected and appropriate control groups found are utilized in order to show data which teaches away from that which has been established in the prior art.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 3, the statement ".....inhibitor of 5 alpha reductase inhibitor or an inhibitor of any subtype of that enzyme.." is unclear as to whether applicant intends an inhibitor of an inhibitor or an inhibitor of an enzyme, given that there is no enzyme set forth in the instant claim.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Chwalisz et al., U.S. Patent No. 5,906,987, 4/25/99.

Grainger et al., U.S. Patent No. 5,770,609, 6/23/99.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Primary Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

JAMES O. WILSON
PRIMARY EXAMINER
GROUP 1600